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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,048

10/12/2004

Benoit Denizot

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EXAMINER

MAEWALL, SNIGDHA

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

11/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,048	Applicant(s) DENIZOT ET AL.	
	Examiner Snigdha Maewall	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/25/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. Receipt of amended claims and IDS filed on 07/25/08 is acknowledged.

Election/Restrictions

2. Applicant's election without traverse of Group I claims 8-13 in the reply filed on 07/31/08 is acknowledged.

Applicant's election of specific species 6-trimethylammoniohexyl-1, 1 bisphosphonic acid is also acknowledged. Applicants have traversed the election of species requirement and argue that there would be no serious burden on examiner to search the disclosed species and the species must be independent and distinct has not been shown by the Examiner.

This is not persuasive for the reasons clearly set forth in the previous Office action. Applicants are essentially claiming millions of compounds and they expect the examiner to search all the claimed compounds and their application in oral preparations. There is no evidence of record that the instant compounds are obvious variants. It is too burdensome for the examiner to search all of the previously noted searches in their respective, completely divergent, areas for the non-elected subject matter, as well, in the limited time provided to search one invention.

The restriction requirement is deemed sound and proper and will be maintained.

This application has been examined to the extent readable on the elected compound i.e. 6-trimethylammoniohexyl-1, 1-bisphosphonic Acid since applicants have failed to submit a claim directed solely to the elected group and species.

Claims 14, 2-7 and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/31/08.

Claim 1 remains cancelled.

Claims 8-13 are under prosecution to the extent they read on the elected species.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 8-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., In re Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was

Art Unit: 1612

not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as hydrophilic group, chemical bond, alkyl, aryl, several hydroxyl alkyl groups containing phosphate groups etc. throughout the claims), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See Univ. of Calif. V. Eli Lilly, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. *If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus*. See MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art,

Art Unit: 1612

partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any *combination of such identifying characteristics that distinguish the claimed invention from other materials* and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful [in oral preparations] generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions. Specifically, the specification discloses only a limited number of species at page [15], lines [10-25], and these are not viewed as being reasonably representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus. Examiner suggests reciting specific species corresponding to the claimed invention of which the applicants were in possession of.

5. Claims 8-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the

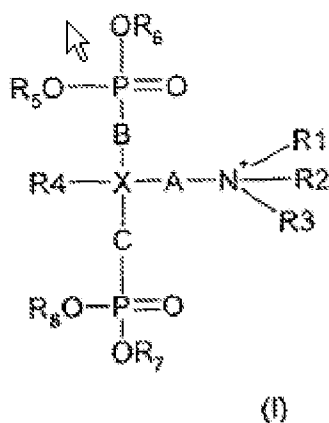
Art Unit: 1612

enablement requirement and whether any necessary experimentation is “undue”.

These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention

The claims are drawn to: an oral hygiene composition with formula I



Wherein:

Art Unit: 1612

R1, R2, R3, R5, R6, R7, R8 represent an atom of hydrogen or an alkyl or aryl group in C1 - C6, independently of each other;

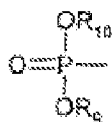
X is a carbon C atom or a nitrogen N atom;

A represents an alkyl or aryl group in C1 - C6, a carbonyl group or a hydrophilic group, B and C represent a chemical bond, an alkyl or aryl group in C1 - C6, a carbonyl group, or a hydrophilic group; and

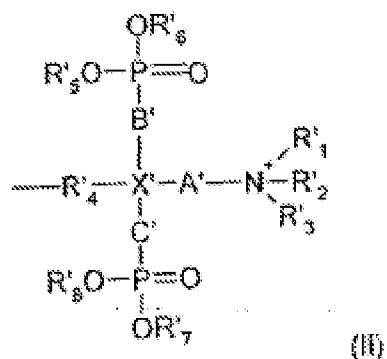
R4 represents:

a hydrogen atom, an OH group, an alkyl or an aryl group in C1 - C6, or a carboxylic acid in C1 - C6, a free doublet (if X is a nitrogen N);

a phosphonate with formula:



With various substituents and formula II



Art Unit: 1612

With various substituents.

State of the Prior Art and the level of skill in the art

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. The level of unpredictability in the art is very high. The compounds which differ by a methyl group also show different properties, for e.g. theophylline and caffeine. One of them is a bronchodilator and they differ only by a methyl group. See *In re Fisher*, 166 USPQ 18, at 24 (In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.), *Nationwide Chemical Corporation, et al. v. Wright, et al.*, 192 USPQ 95 (one skilled in chemical and biological arts cannot always reasonably predict how different chemical compounds and elements might behave under varying circumstances), *Ex parte Sudilovsky* 21 USPQ2d 1702 (Appellant's invention concerns pharmaceutical activity. Because there is no evidence of record of analogous activity for similar compounds, the art is relatively unpredictable) *In re Wright* 27 USPQ2d 1510 (the physiological activity of RNA viruses was sufficiently unpredictable that success in developing specific avian recombinant virus vaccine was uncertain).

The level of skill is very high.

The breadth of the claims

Art Unit: 1612

The instant claims encompass composition comprising polyphosphonate with many substituents hanging off of it.

The claims disclose various species with various substituents. The specification only provides preparation of one species. In the absence of guidance provided in specification, one skilled in the art would undergo undue experimentation while practicing the invention. The disclosure provides no guidance as how to prepare various claimed polyphosphonates with multiple substituents.

Predictability/unpredictability of the art.

There is no absolute predictability even in view of the seeming high level of skill in the art. The existence of these obstacles established that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any treatment regimen on its face.

The amount of direction or guidance and the presence or absence of working examples

Applicant may not preempt unduly large field by expedient of making broad prophetic statements in specification and claims unless accuracy of such statements is sufficiently supported by well established chemical principles or by sufficient number of examples.

“The term ‘substituted’ without modification or restriction includes all compounds wherein one or more of the atoms or radicals of the original compound have been replaced by one or more other atoms or radicals. Without any limitation on the character or number of substituents it becomes apparent that the quoted term may be considered

Art Unit: 1612

inclusive of almost any possible substance and the claims under consideration are either of unlimited or indeterminate scope. We are of the opinion that the reasoning of the courts in *Schering Corp. v. Gilbert*, 68 USPQ 84, and *Hercules Powder Co. v. Rohm & Haas*, 70 USPQ 297, is controlling.”

embrace millions of compounds. It should also be observed that appellant is working in a field where little prediction is possible and this Board has on several occasions held that the scope of claims should not be unduly extensive in fields where applicability is highly speculative or not explored and that subject matter which relies upon prediction for its support is unpatentable. *Ex parte Middleton*, 87 USPQ 57; *Ex parte Kauck et al.*, 95 USPQ 197 , *Ex parte Rosenkranz et al.*, Pat. No. 2,715,637.

In *Minnesota Mining and Mfg. Co. et al. v. Carborundum Co. et al.*, 155 F.2d 746, 69 USPQ 288 , the court held that “An inventor cannot disclose a small number of components which will serve as a springboard for claiming an entire class.”

In addition *In re Fouche* 169 USPQ 429 dealt with a similar issue with respect to how to use requirement of 112 1st paragraphs,

“Inclusion of representative examples is not required to enable a person skilled in the art to use a generic invention; nevertheless, applicant must use some technique of providing teaching of how to use which is commensurate with breadth of protection sought by claim, unless such knowledge is already available to persons skilled in the art; thus, where applicant undertakes to define invention by recitation of a Markush group, he must enable one skilled in the art to make and use at least one composition employing each member of group.

Art Unit: 1612

Both the examiner and the board noted that none of the working examples pertained to compounds wherein Z was heterocyclic. Appellant is quite correct in contending that, under our decisions in *In re Robins*, 57 CCPA 1321, 429 F.2d 452, 166 USPQ 552 (1970), the inclusion of representative examples is not required to enable a person skilled in the art to use a generic invention. Nevertheless, an applicant must use *some* technique of providing teaching of how to use which is commensurate with the breadth of protection sought by the claim, unless such knowledge is already available to persons skilled in the art.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure:

In view of all the above factors, guidance and state of the art , it would require an undue amount of experimentation to make the invention of the claims with various substituents , or for using them to oral hygiene products.

Taking the above eight factors into consideration, it is not seen where the instant specification enables the ordinary artisan to make and/or use the instantly claimed invention. MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue Experimentation will be required to practice Applicants' invention.

The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. Applicants are referred to In re Fouche, 169 USPQ 429 CCPA 1971, MPEP 716.02(b). Applicants are also referred to In re Wands, 858 f.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte Foreman, 230 USPQ 546 (Bd. Of App. and Inter 1986).

In terms of the 8 Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of unpredictability in the art of the invention, and the poor amount of direction provided by applicants. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.”

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1612

7. Claims 8-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "one or several hydroxyl". The claim is indefinite as it is not clear when applicant intends to claim one or many. Claim 5 recites the limitation "protected by a group that becomes a hydrophilic group again after a biological hydrolysis" is vague and indefinite. It is not clear which group applicant is referring. Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aymard et al. (EP216681) (presented in IDS).

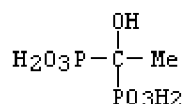
Aymard et al. teach process for Process for preparing cationic dispersing agents (title). Cationic dispersing agents are prepared by the reaction of a compound containing OH and phosphono groups with a compound containing a quaternary N and a group reactive with phosphono groups. The dispersing agents are useful in the paper, textile, and coating industries. Treatment of 315 parts 55% aqueous 1-hydroxy-1,1-diphosphonoethane at 50° with 110 parts 2,3-epoxypropyltrimethylammonium chloride

Art Unit: 1612

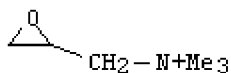
during 10 min, heating 2 h at 50°, and heating to 100-105° during 5 h gave 425 parts

$\text{HOCH}_2\text{P}(\text{O})(\text{OH})_2\text{P}(\text{O})(\text{OH})\text{OCH}_2\text{CH}(\text{OH})\text{CH}_2\text{N}^+\text{Me}_3 \text{Cl}^-$ which was used as a

pigment dispersant in the manufacture of paper.



IT 3033-77-0, 2,3-Epoxypropyltrimethylammonium chloride
(esterification of, by hydroxyalkanediphosphonic acid)
RN 3033-77-0 HCAPLUS
CN 2-Oxiranemethanaminium, N,N,N-trimethyl-, chloride (1:1) (CA
INDEX
NAME)



IC ICM C07F009-40
ICS D21H003-02
CC 46-4 (Surface Active Agents and Detergents)
Section cross-reference(s): 23, 40, 42, 43
IT 2809-21-4, 1-Hydroxy-1,1-ethanediphosphonic acid 16856-53-
4,
1-Hydroxy-1,1-butanediphosphonic acid
(esterification of, by epoxypropyltrimethylammonium
halide)
IT 3033-77-0, 2,3-Epoxypropyltrimethylammonium chloride
13895-77-7
(esterification of, by hydroxyalkanediphosphonic acid)

The reference teaches preparation of the claimed TMADP compound and discloses TMADP's utility in textile, paper and coating industries as disclosed above (abstract and Chemical Registry No.) It is therefore apparent that the water is utilized in textile and paper applications. Based on the teachings of the cationic dispersant properties and the applications of TMADP, it would have been obvious to one of ordinary skill to utilize the cationic dispersant in oral preparations and come to the claimed invention with the reasonable expectation of success. One would have been motivated to prepare and use in oral applications other polyphosphonates such as 6-trimethylammoniohexyl-1 based on the teachings of the disclosed reference with an expectation to obtain another cationic dispersant to be used in oral preparations. With respect to various amounts of polyphosphonate, it is the position of the examiner that optimization of such parameter would have been within the purview of a skilled artisan.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

Art Unit: 1612

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/
Examiner, Art Unit 1612
/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612